

that there must be a serious burden placed on the Examiner by not requiring restriction. If either criterion is not met, restriction is not proper (see, MPEP § 803). Thus, even if an application contains claims that are independent or distinct, the lack of a serious burden for a search of the subject matter requires that an examination on the merits be carried out on all of the claims without restriction. As noted in the MPEP:

“If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.” (MPEP § 803, emphasis added).

In the Office Action, the Examiner restricted the claims of the application into three groups:

Group I: Claims 1-50, as drawn to a process for insulating nucleic acids comprising use of a surface charged from a given direction

Group II: Claims 51-55 and 58, as drawn to a process for isolating nucleic acids on one side of a membrane

Group III: Claims 56 and 57, as drawn to an apparatus for isolating nucleic acids

Applicants respectfully traverse the restriction requirement of the pending claims for the reasons set forth below.

With respect to Groups I and II, the Examiner stated:

“Inventions of Group I-II are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Group I-II comprise steps which are not required for or present in the methods of the other group: charging a surface from a given direction (Group I) and isolating nucleic acids on one side of a membrane (Group II). Thus, the operation, function and effects of these different methods are different and distinct from each other. . .” (p. 3, Office Action, Paper No. 5)

Applicants' invention is based on the inventive feature of isolating nucleic acids by immobilizing the nucleic acids on one side of a surface followed by a release (elution) of the

immobilized nucleic acids from the same side of the surface from which the nucleic acids were applied and immobilized (see, e.g., p. 5, lines 4-5; p. 12, lines 3-5). Thus, according to the invention, the isolated nucleic acids never pass through the surface on which they are immobilized and from which they are eluted. This inventive feature is clearly present in all of the process claims (i.e., Claims 1-55 and 58). For example, Claim 1 (and, thereby Claims 2-49), comprises the steps of:

- charging a surface from a given direction with nucleic acids;
- immobilizing the nucleic acid on the surface;
- releasing the immobilized nucleic acids from the surface, and
- removing the released nucleic acids from the surface, essentially in the same direction of the charging (emphasis added).

Applicants note that the term “charging” is a familiar term of art that is synonymous with “loading” (see, e.g., p. 4, line 11 of the specification). More importantly, Applicants note that Claim 1 clearly indicates that nucleic acids are removed from a surface in the same direction from which they were loaded on the surface (and immobilized and released, as well). Likewise, Claim 51 (and thereby Claims 52-55 and 58), which is directed to an embodiment wherein the surface on which the nucleic acid is immobilized is a membrane, also specifically states that the nucleic acid is immobilized and released from the same side of that membrane surface. Clearly, the inventive feature of isolating nucleic acid in a process in which the nucleic acid is immobilized and released from the same side of a surface is present in all of the process claims of this application. Therefore, only a single search should be required for the inventive feature of both Claim 1 (and claims dependent therefrom) and Claim 50 (and claims dependent therefrom). Accordingly, a search of the subject would not place an undue or serious burden on the Examiner, and division of process Claims 1-55 and 58 is unnecessary and improper.

Claims 56 and 57 cover an apparatus specifically designed to isolate nucleic acids according to a process of the invention. The Examiner stated:

“Inventions of Group I and Group III are related as process and apparatus for its practice . . . In this case, the apparatus as claimed can be used to practice another materially different process, isolating *any charged molecule, including those unrelated to nucleic acids*.

“The apparatus of Group III is limited to being used for the method of Group I, not Group II, and thus the inventions of Groups II-III are different and distinct and capable of supporting separate patents.” (p. 3, Office Action, Paper No. 5)

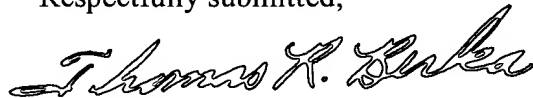
Applicants first note that Claims 55 and 56 are specifically directed to an apparatus for automatically performing a process of isolating nucleic acids according to any one of Claims 1-49. Thus, Claims 55 and 56 comprise the inventive feature found in process Claims 1-49, i.e., a process of isolating nucleic acids comprising immobilizing and eluting the nucleic acid from the same side of a surface. As explained above, this same inventive feature is present in all of the process claims. However, the Examiner has speculated that the apparatus of Claims 55 and 56 could be used to isolate charged molecules that are unrelated to nucleic acids (see emphasis in above quote). The Examiner's view is clearly not based on Applicants' specification, which discloses an invention based on an understanding of the molecular and biochemical properties of nucleic acids. In fact, Applicants have provided actual working examples of isolating nucleic acids according to the invention from cell lysates that clearly contain numerous molecules unrelated to nucleic acids (see, e.g., Example 1, p. 16, line 10-p. 18, line 10 of the specification; Example 3, p. 19, line 16-p. 22, line 3 of the specification; Example 5, p. 24, line 5-p. 25, line 3 of the specification; "real time" quantitative RT-PCR and PCR detection assay in Example 16, p. 33, line 7-p. 34, line 23 of the specification; and Examples 17 and 18, p. 34, line 25-p. 37 of the specification. Thus, the Examiner's view that the inventive feature of Applicants' invention would also purify molecules unrelated to nucleic acids is clearly contrary to Applicants' own results disclosed in the application. Without more to support the Examiner's view, Applicants respectfully submit that there is no reasonable basis for dividing Claims 55 and 56 from the other claims of this application (see also, last paragraph of MPEP § 806.05(f)).

Furthermore, given that Claims 55 and 56 share the same inventive feature of isolating nucleic acids in a process comprising immobilizing and eluting nucleic acid from the same side of a surface, a search for Claims 55 and 56 would not present an undue or serious burden to the Examiner. Accordingly, division of Claims 55 and 56 from the process claims of this application is unnecessary and improper.

In view of all of the above comments, Applicants respectfully submit that Claims 1-58 are clearly related by the same inventive feature. Thus, all of the claims are seen to relate to a single inventive feature, and the claims are in a form and are of the sort that is properly viewed as relating to a single invention that should not be restricted. Moreover, since all of claims share the same inventive feature, a search of the claimed subject matter would not present a serious burden to the Examiner for the purposes of examination on the merits. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement of Claims 1-58 into Groups I-III.

Although Applicants believe that restriction of the claims is improper, without in any way acquiescing or conceding to the reasons for the restriction requirement set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination of the claims of Group I, i.e., Claims 1-50.

Respectfully submitted,



Leon R. Yankwich; Registration No. 30,237
Thomas R. Berka, Ph.D., Registration No. 39,606
Attorneys for Applicants
YANKWICH & ASSOCIATES
130 Bishop Allen Drive
Cambridge, Massachusetts 02139
telephone: (617) 491-4343
telefax: (617) 491-8801

CERTIFICATE OF MAILING

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service as First Class mail, in an envelope addressed to the Asst. Commissioner for Patents, Washington, DC 20231, on the date indicated below.

July 5, 2001
Date of mailing and signature


Stephanie L. Leicht